

Phonetic and Orthographic Computer Analysis (POCA)

POCA v4.2 USER GUIDE



Version 1.0

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Table of Contents

Contents

Phonetic and Orthographic Computer Analysis (POCA)	1
VersionHistory.....	1
Organization Overview	5
1 Introduction.....	6
1.1 Background	6
1.2 Document Scope	6
2 Getting Started	8
2.1 Requesting an Account	9
2.2 Home Page and Navigation	10
2.2.1 NavigationBar	11
2.2.2 NewSearch/RetrieveArchived SearchBar	11
3 Settings for All Users.....	14
3.1 Set your Returned Results Threshold	14
3.2 Set Your Number of Results per Page	15
4 Settings for Business andSystem Admin Users	16
4.1 Add/Edit a User	16
4.2 Add/Edit News Items.....	18
4.3 UAR Report	19
4.4 Edit Account Request Email Address	20
4.5 Edit Feedback Email Address	20
5 Advanced Settings – System Administrators	22
5.1 Data source Maintenance.....	22
5.2 Modify Datasource Names.....	22
6 Advanced Settings – BusinessAdministrators.....	23
6.1 Manually Add Name to Database.....	23
6.2 Delete Drug Name.....	23
6.3 View SE Drug Names	24

6.4	Manage Biologic suffixes data source.....	25
7	Drug Name Searches - All Users.....	27
7.1	Search Algorithms.....	27
7.2	Accessing the Search.....	28
7.3	Search View.....	28
7.4	Search Results	29
7.5	Export To Excel	31

Table of Figures

Figure 1: Settings Page for Safety Evaluators	7
Figure 2: Settings Page for Business Administrators	7
Figure 3: Settings Page for System Administrators.....	8
Figure 4: Login Screen	9
Figure 5: Request Account Screen	9
Figure 6: Home Page	10
Figure 7: Drug Name Search Section in Home Page	12
Figure 8: Direct Search section in Home Page	12
Figure 9: Multiple Direct search home page.....	13
Figure 10: Personal Settings for a System Administrator	14
Figure 11: Setting the Threshold for Returned Results.....	14
Figure 12: Number of results per page	15
Figure 13: Add/Edit user	16
Figure 14: Edit User Screen	17
Figure 15: Add/Edit News Item page	18
Figure 16: Edit a New Item.....	19
Figure 17: UAR Report	20
Figure 18: Edit Account Request Email Screen	20
Figure 19: Edit feedback email address	21
Figure 20: Data Source Maintenance Screen.....	22
Figure 21: Modify datasource names	22
Figure 22: Manually Add Name to Database	23
Figure 23: Delete drug name (1 of 2)	23
Figure 24: Delete a Record Screen (2 of 2)	24
Figure 25: View SE Drug Names screen	24
Figure 26: Manage Biologic Suffixes Data Source Page	25
Figure 27: Adding Biologic suffix	26
Figure 28: Modify Biologic Suffix	26
Figure 29: search algorithm	27
Figure 30: Drug Name Search	29
Figure 31: Search Results Example	30
Figure 32: Product Details Page	31
Figure 33: Export to Excel examples	32
Figure 34: Excel file 'Save as ' in the local drive	32

Organization Overview

This document is organized into seven main sections.

- **Section One (Introduction)** discusses the background, scope, and organization.
- **Section Two (Getting Started)** contains instructions on connecting to the system, logging on, requesting accounts, and navigation from the home page.
- **Section Three (Settings for All Users)** provides information on system wide settings available to all POCA user roles.
- **Section Four (Advanced Settings for Business and System Admin. Users)** describes information on system wide settings available to System Administrators and Business Administrators users.
- **Section Five (Advanced Settings – System Administrators)** provides information on system wide settings accessible to the System Administrators user group.
- **Section Six (Advanced Settings – Business Administrators)** provides information on system wide settings accessible to the Business Administrators user group.
- **Section Seven (Drug Name Searches – All Users)** provides information about how to perform drug name searches.

1 Introduction

1.1 Background

A vital part of the Food and Drug Administration (FDA) and Center for Drug Evaluation and Research (CDER)'s mission is to develop new standards to prevent medication errors due to proprietary name confusion. The Office of Surveillance and Epidemiology (OSE), Division of Medication Errors Prevention and Analysis (DMEPA) contributes to this effort by evaluating all proprietary names submitted to CDER for similarity to other marketed names, as well as other proposed names currently under review. In December 1999, the Institute of Medicine (IOM) Report recommended testing of proposed proprietary names to prevent confusion and medication errors with existing drug names. The Quality Interagency Coordination Task Force (QuIC) reporting to the President in February 2000 endorsed the IOM recommendation.

In response to these reports, FDA devoted greater resources to the area of drug name confusion analysis. Proprietary name confusion may stem from the manner in which a name is pronounced or scripted. The Phonetic and Orthographic Computer Analysis System (POCA) is a web application developed to determine written (orthographic) and spoken (phonetic) similarities between proposed drug names.

1.2 Document Scope

This User Guide provides information for safety evaluators, business administrators, and system administrators. It is not a technical developer's manual, nor does it provide in-depth information on the database or operating systems.

This document refers to three types of user groups and the scope of their access to the database as described below:

Safety Evaluator User Group

Access Level includes:

- Conduct Searches
- Retrieve Archived Searches

Settings for safety evaluators include as per the screen below:

[Return To Home Page](#)

Your Settings

[Set your returned results threshold](#)
[Set your number of results per page](#)

Figure 1: Settings Page for Safety Evaluators



Business Administrator User Group

Access Level includes:

- Conduct Searches
- Retrieve Archived Searches
- Manually Add Drug Names To Database
- Manage Biologic Suffixes Data Source
- Delete Drug Names from Database
- Add/Edit users
- UAR Report

Settings for business administrators include as per the screen below: |

Welcome Arka Biswas. Today is 08-08-2017

POCA 4.2
Phonetic and Orthographic Computer Analysis

[Return To Home Page](#)

Your Settings

[Set your returned results threshold](#)
[Set your number of results per page](#)

Advanced Settings

User Add/Edit a User Add/Edit News Items UAR Report	Datasources/Records Delete Drug Name View SE Drug Names Manage Biologic Suffixes Data Source
System Edit Account Request Email Address Edit Feedback Email Address	

Figure 2: Settings Page for Business Administrators

System Administrator User Group

Access Level includes:

- Conduct Searches
- Retrieve Archived Search
- Datasources Maintenance
- Modify Datasource Names
- Add/Edit users
- UAR Report

Settings for System Administrators include as per the screen below:

Return To Home Page**Your Settings**

Set your returned results threshold
Set your number of results per page

Advanced Settings**User**

Add/Edit a User
Add/Edit News Items
UAR Report

Datasources/Records

Datasource Maintenance
Modify Datasource Names

System

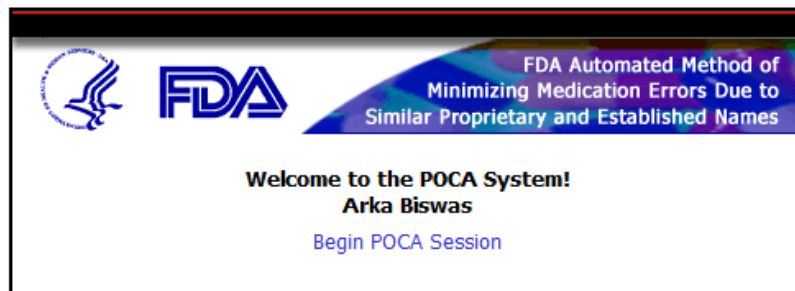
Edit Account Request Email Address
Edit Feedback Email Address

Figure 3: Settings Page for System Administrators

2 Getting Started

To access POCA, open your web browser (Internet Explorer, Chrome, Firefox or any other browser). Internet Explorer is opened by double clicking on the browser icon on your desktop or by selecting Start, Programs, and Internet Explorer from the start menu. In the address bar of your web browser, type the universal resource locator (URL) for POCA as <http://poca.fda.gov/poca>.

You will need a user account to access POCA. If an account has been created for you, then the Login screen will appear as shown below with “Begin POCA Session” link. Since the POCA system is Single Sign-On (SSO) enabled, and does not require users to enter a user name and password. Click on the link “Begin POCA Session” to login to POCA. After successful login, POCA Home page will be displayed as in section 2.2.

**Disclaimer**

This is a Federal computer system and is the property of the United States Government. It is for authorized use only. Users (authorized or unauthorized) have no explicit or implicit expectation of privacy.

Any or all use of this system and all files on this system may be intercepted, monitored, recorded, copied, audited, inspected, and disclosed to authorized site, Food and Drug Administration, and law enforcement personnel, as well as authorized officials of other agencies, both domestic and foreign. By using this system, the user consents to such interception, monitoring, recording, copying, auditing, inspection, and disclosure at the discretion of authorized site or Food and Drug Administration personnel.

Unauthorized or improper use of this system may result in administrative disciplinary action and civil and criminal penalties. By using this system you indicate your awareness of and consent to these terms and conditions of use.

Figure 4: Login Screen

If you do not have a POCA account, then the Login Screen will appear as shown below with “Request Account” link. Please click on the “Request Account” link and follow the steps below to request an account.

2.1 Requesting an Account

You may request a POCA account by clicking on the “Request Account” link on the login screen. The *Request an Account* screen will be displayed.

The image shows the "Request an Account" screen. At the top, there is a header with the FDA logo on the left and the text "Request an Account" on the right. Below the header, there is a link "Return to Login Screen". The main content area contains the text: "If you would like to request an account, enter your name and email address. The system administrator will contact you shortly with login information." Below this text, there are two input fields: "Please enter your name:" and "Please enter your email address:". At the bottom right, there is a "Submit" button.

Figure 5: Request Account Screen

Enter your name and FDA email address in the text boxes provided, and click the “Submit” button. An email will be sent to a POCA administrator stating that a POCA account is being requested for you. The POCA administrator will add your account to POCA with the Safety Evaluator user role unless a different role is requested. The POCA administrator will contact you via e-mail with your login information and you will also receive POCA email after your account is created. At that point, you may log in by typing <https://poca.fda.gov/poca> in your browser. Upon successful log in, the home page is displayed for the assigned role to you.

2.2 Home Page and Navigation

The home page is the main control panel for the system. From the homepage users can access all of the functionality of the system. Specific sections of the home screen and their purpose are described below.

Welcome Arka Biswas. Today is 08-08-2017

Home | Search | Settings | Comments | Help | End Session

POCA 4.2
Phonetic and Orthographic Computer Analysis

New Search | Retrieve Archived Search

Drug Name Search

* % For wildcard searching
_ For single character searching

Search Text:

Search Type:

☒ Orthographic
☒ Phonetic
☐ Text*

Databases:

Datasource	Date Updated	Product Count
<input type="checkbox"/> Drugs At FDA	05-25-2017	6,875
<input type="checkbox"/> RxNorm	05-09-2017	27,779
<input checked="" type="checkbox"/> Name Entered by Safety Evaluator	10-03-2016	836
<input type="checkbox"/> Biologic Suffixes Entered by Safety Evaluator	08-03-2017	7
<input type="checkbox"/> Cerner--US Legend and OTC	09-14-2007	13,072
<input type="checkbox"/> DFRF	12-12-2007	3
<input type="checkbox"/> Orange Book - approved since 1980	04-20-2017	6,606
<input type="checkbox"/> cder biologic	08-13-2008	350

Reset Submit

News

POCA Version 4.2 in Test
POCA Version 4.2 in Test

Manually Add Name to Database

Add

Multiple Name Direct Search

Open Direct Search Page

Single Name Direct Search

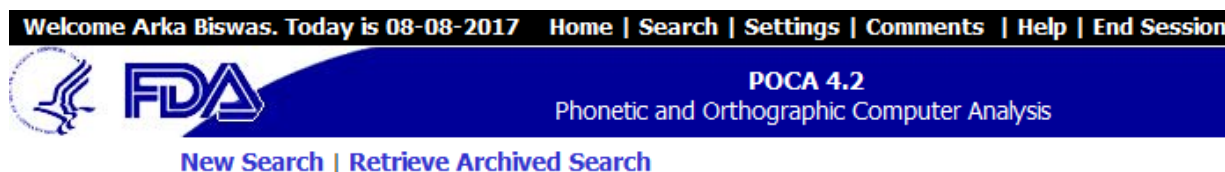
Candidate Drug:
Comparator Drug:

Reset Submit

Figure 6: Home Page

2.2.1 Navigation Bar

At the top right hand portion of the home page you will find a navigation bar with links for accessing major parts of the POCA application, such as the home page, search page and settings page. The navigation bar has other links such as comments and help. This navigation bar is accessible on all POCA pages.



2.2.2 New Search/Retrieve Archived Search Bar

Another option to navigate to the search page is the “New Search” link located at the top of the home page, below the FDA banner.



The *New Search link* is available for all users. This will allow you to search for a drug name.

The *Retrieve Archive Search link* is available for all users. Clicking the link will display a search page that can be used to search for previously conducted searches.

2.2.3 News

News and announcements are displayed for all users. To view more information about the news item, the user can click on the news title.



2.2.4 Drug Name Search

Drug Name Search is displayed for all users. Users can perform Orthographic, Phonetic or Text searches for any drug name within the selected data sources. More about how to use the *Drug Name Search* feature is described in section 7.

Datasources:

	Datasource	Date Updated	Product Count	
<input checked="" type="checkbox"/>	Drugs At FDA	05-25-2017	6,875	
<input checked="" type="checkbox"/>	RxNorm	05-09-2017	27,779	
<input checked="" type="checkbox"/>	Name Entered by Safety Evaluator	10-03-2016	836	
<input checked="" type="checkbox"/>	Biologic Suffixes Entered by Safety Evaluator	08-03-2017	7	
<input type="checkbox"/>	Cerner--US Legend and OTC	09-14-2007	13,072	
<input type="checkbox"/>	DPRF	12-12-2007	3	
<input type="checkbox"/>	Orange Book - approved since 1980	04-20-2017	6,606	
<input type="checkbox"/>	cber biologic	08-13-2008	350	

Reset Submit

Figure 7: Drug Name Search Section in Home Page

2.2.5 Direct Search

The direct search functionality is available to all users. This feature provides users the ability to perform direct searches between Candidate Drug Names and Comparator Drug Names. After entering those 2 drug names and pressing the Submit button, the Combined, Phonetic and Orthographic search result scores will be displayed for those 2 drug names.

Direct Search

Candidate Drug:

Comparator Drug:

Reset Submit

Combined Score: **69**
 Phonetic Score: **69**
 Orthographic Score: **72**

Figure 8: Direct Search section in Home Page

2.2.6 Multiple Direct Search

The Multiple Direct Search functionality is available to all users. This feature provides users the ability to perform direct searches between Candidate Drug Names and multiple Comparator Drug Names. Click on "Open Direct Search Page" under the "Multiple Name Direct Search" section.

Multiple Name Direct Search

A new page will appear with Candidate Drug and Comparator Drugs text fields. To use this search function, follow the instructions below:

- Enter a name in the Candidate Drug text field
- Enter multiple drug names in the Comparator Drugs text field, each separated by commas. Click on the “information” button - that will display popup message about Comparator Drugs text field format.
- Click the Submit button once all names have been entered in the text fields.

After clicking on the Submit button, the Combined, Phonetic and Orthographic search result scores will be displayed as illustrated in Figure 9 below.

Candidate Drug:

Comparator Drugs:

Total Drug Name Pairs: 57

Drug Name Pair	Orthographic Score %	Phonetic Score %	Combined Score %
tylenol - 1-Butanol	61	59	60
tylenol - 2-Phenylphenol	68	53	60
tylenol - 3-Nonylphenol	75	51	63
tylenol - 4-Nonylphenol	75	51	63
tylenol - 4-Terpineol	69	56	62
tylenol - Altenol	79	63	71
tylenol - Bal In Oil	53	68	60
tylenol - Calimal	48	78	63
tylenol - Calomel	50	74	62
tylenol - Caplenal	53	67	60
tylenol - Celectol	63	65	64
tylenol - Clinsol	57	74	66
tylenol - Cutemol	61	62	62
tylenol - Deanol	65	63	64
tylenol - De-Nol	71	57	64

Page 1 [2] [3] [4]

Figure 9: Multiple Direct search home page

2.2.7 Manually Add Drug Name to Database

This functionality is available to business administrator users only and allows them to manually add drug names to “Name Entered by Safety Evaluator” data source. Please see Section 6.1 for more information.

Manually Add Name to Database

3 Settings for All Users

All personal settings for your POCA account can be accessed from *Your Settings* section on the *Settings* screen. To access the *Your Settings* screen, click on the “Settings” link found in the navigation bar. Each role will see different functionality in Settings page as described in section 1.2.

[Return To Home Page](#)

Your Settings

[Set your returned results threshold](#)
[Set your number of results per page](#)

Figure 10: Personal Settings for a System Administrator

The following settings are available to all users.

3.1 Set your Returned Results Threshold

Users can set the threshold for returned results by clicking the “Set your returned results Threshold” option under *Your Settings*.

Enter a threshold for returned results per module: %

Figure 11: Setting the Threshold for Returned Results

The threshold is the percentage match required for a result to be returned by the search engine. For example: If the threshold is set to 50%, only results with a match percentage of 50% or higher will appear in the result set.

3.2 Set Your Number of Results per Page

POCA allows users to set the default number of results displayed per page by clicking on the “Set Your Number of Results per Page” link under *Your Settings*. When a user conducts a search, the default number of results will be displayed per page. If there are more results returned than the default number of results, the user will have the ability to scroll through the pages of results.

Enter the number of results to return per page per module:

Figure 12: Number of results per page

4 Settings for Business and System Admin Users

Business Administrators and System Administrators user groups have the same advanced settings except for their level of access to ‘Datasource/Records’. The table below shows the level of access for each type of administrator under Datasource/Records:

Administrator User Group	Datasources/Records Level of Access
System Administrator	Datasource Maintenance Modify Datasource Name
Business Administrator	Delete Drug Name View SE Drug Names Manage Biologic Suffixes Data Source

The following settings are available to all business and system administrator users.

4.1 Add/Edit a User

To add or edit a user profile, click the “*Add/Edit a User*” link under *Advanced Settings* on the *Settings* page. To access the *Advanced Settings* screen, click on the “*Settings*” link found in the navigation bar. The User Administration page will be displayed as shown below.

[Return to Settings](#)

Edit User:

Select a user from the list below to edit their details.

Enabled Users:	<input type="text" value="adinka@ppc.com"/>	<input type="button" value="Edit User"/>
Disabled Users:	<input type="text" value="adriana.gonzalez@fda.hhs.gov"/>	<input type="button" value="Edit User"/>

Add a new user:

User Name:	<input type="text"/>
First Name:	<input type="text"/>
Last Name:	<input type="text"/>
Email:	<input type="text"/>
User Group:	<input type="text" value="Business Administrator User Group"/>
<input type="button" value="Add User"/>	

Figure 13: Add/Edit user

To add a new user profile, fill out the form that appears under the *Add a new user* heading. All input fields available on the form are described in the table below.

Field Name	Definition/Description	Field Type
User Name	Enter a username for the new account. The username will be used by the user to log in to POCA. This field is required.	Edit
First Name	Enter the first name of the user. This field is required.	Edit
Last Name	Enter the last name of the user. This field is required.	Edit
Email	Enter the email address of the user, and be sure to check for typos. It is important to type this field correctly. The application will use this field to send electronic Notifications to the user. This field is required.	Edit
User Group	Select from the list if the user is a <i>Safety Evaluator</i> , <i>Business Administrator</i> or <i>System Administrator</i> .	Pick list

When editing a user profile, please note that there are two pick lists for existing user profiles, one for enabled accounts, and another for disabled accounts. You can choose an account to edit by selecting from either list the username corresponding to the user profile you wish to edit, and clicking the “Edit User” button. Once a user is selected for editing, the *Edit User* form will be displayed with all the information available. An example of the *Edit User* form following the selection of username *arka.biswas1* for editing appears as illustrated in Figure 14 below.

Edit User

User Name:	arka.biswas1
First Name:	<input type="text" value="Arka"/>
Last Name:	<input type="text" value="Biswas"/>
Email:	<input type="text" value="arka.biswas@fda.hhs.gov"/>
User Group:	<input type="text" value="Business Administrator User Group"/> ▼

<input type="button" value="Update User"/>	<input type="button" value="Disable User"/>
--	---

Figure 14: Edit User Screen

The *Edit User* form allows the editing of the First Name, Last Name, Email, and User Group associated with a user. When you are done editing these fields, click “Update User” to submit these changes to the POCA database.

In addition, the *Edit User* form for the enabled user account can be used to disable user accounts. To disable the enabled user account, simply click the “Disable User” button on the *Edit User* page. A disabled account cannot be used to log in to POCA, but all data associated with the disabled user will be preserved.

Similarly, the *Edit User* form for the disabled user account can be used to enable user accounts. To enable the disabled user account, simply click the “Enable User” button on the *Edit User* page.

4.2 Add/Edit News Items

News Items display on the home page of the POCA system under News section. Existing news items can be edited, and additional news items can be created by clicking the “Add/Edit News Items” link in the list of *Advanced Settings* on the *Settings* screen. To add a news item, populate the *Headline*, *News Teaser*, *News Item*, and *Expire Date* fields in the form that appears below, and click the “Submit/Update” button. Click “Reset” to clear the form.

[Return to Settings](#)

Select a news item from the list to edit it: POCA Version 4.2 in Test ▼

Get News Item

Headline:

News Teaser:

News Item:

Expire Date:

Submit/Update

Reset

Figure 15: Add/Edit News Item page

The fields on this form are described below table.

Field Name	Definition/Description	Field Type
------------	------------------------	------------

Headline	This is the title that will identify the news item. This field is required.	Edit
News Teaser	Text entered here will appear below the headline on the home and login pages. This field is required.	Edit
News Item	This is the main text of the news item. This field is required.	Edit
Expire Date	The “expire date” determines when a news item will no longer be displayed on the home and login screens. Enter a date in the format MM-DD-YYYY. This field is required.	Edit

To edit an existing news item, select a news item in the drop down list at the top of the screen, and click the ‘*Get News Item*’ button. Edit the information that appears in the form, and click “Submit/Update” when you are satisfied with the information you entered.

Select a news item from the list to edit it:

Headline:

News Teaser:

News Item:

Expire Date:

Figure 16: Edit a New Item

4.3 UAR Report

Administrator users can view a list of all users, enabled users and disabled users with their full name, e-mail addresses, status, and user group assignment from this feature. You can export the user’s list into a Microsoft Excel by clicking on the ‘Export to Excel’ button.

You also can filter user’s list for a specific time frame.

User Access Report

Enter Begin Date: (mm/dd/yyyy)

Enter End Date: (mm/dd/yyyy)

All	Enabled	Disabled			
Total All Users: 8					
User Name	Full Name	Email	User Group	Status	Create/Update Date
brad.pitt	Brad Pitt	brad.pitt@fda.hhs.gov	System Administrators	Enabled	12/18/2014
brennanc	Colleen Brennan	colleen.brennan@fda.hhs.gov	Business Administrators	Enabled	12/18/2014
jacksongr	Gregory Jackson	gregory.jackson@fda.hhs.gov	System Administrators	Disabled	12/10/2014
BISWASH	Hitlar Biswas	hitlar.biswas@fda.hhs.gov	Safety Evaluators	Enabled	12/18/2014
kurtzigr	Rebecca Kurtzig	rebecca.kurtzig@fda.hhs.gov	System Administrators	Enabled	11/20/2014
DESU	Suranjan De	suranjan.de@fda.hhs.gov	System Administrators	Enabled	11/25/2014
favaw	Walter Fava	Walter.Fava@fda.hhs.gov	Business Administrators	Enabled	12/18/2014
sumita.biswas	sumita biswas	sumita.biswas@fda.hhs.gov	Business Administrators	Enabled	12/18/2014

Figure 17: UAR Report

4.4 Edit Account Request Email Address

When a user account is requested, an automatically generated email is sent to the *account request email address* stored in the POCA database. This email address can be changed using the “*Edit Account Request Email Address*” link in Settings page. It will display the page as shown in Figure 18 below.

[Return to Settings](#)

Enter the email address to send account requests to:

Figure 18: Edit Account Request Email Screen

To have POCA send account requests to multiple email addresses, enter the email addresses separated by semicolons (;). Click “Submit” to store your changes to the POCA database.

4.5 Edit Feedback Email Address

When a user fills out and submits the *Comments and Feedback* form, POCA will send an

automatically generated email to the *Feedback Email Address* stored in the database. This email address can be changed using the “*Edit Feedback Email Address*” link in Settings page. It will display the page as shown below.

Enter the email address to feedback comments to:

Figure 19: Edit feedback email address

To have POCA send feedback and comments to multiple email addresses, enter the email addresses separated by semicolons (;). Click “Submit” to store your changes to the POCA database.

5 Advanced Settings – System Administrators

5.1 Datasource Maintenance

For members of the System Administrators group, the POCA system supports capability to identify, load, refresh, and delete datasources from the POCA database. The data access process begins with the Datasource Maintenance screen, illustrated in Figure 20 below, which can be accessed by clicking the “Datasource Maintenance” link in the Advanced Settings section of the Settings page.

[Return To Settings](#)

Will this be a data load or a data refresh? ☒ Refresh ☐ Load (If a partial data set is used to load, all other records will be deleted.)

Select the datasource type: Cerner--US Legend and OTC ▼

Enter the date of this data: (mm/dd/yyyy)

Next >>

Figure 20: Data Source Maintenance Screen

Select the datasource type, enter the date of the data in the format “MM-DD-YYYY”, and check if you wish to load or refresh the data source. Click the “Next” button, and follow the directions provided.

5.2 Modify Datasource Names

To rename a datasource in the POCA database and to also add new datasources, click on the “Modify Datasource Names” link in the *Advanced Settings* section of the *Settings* page, as illustrated in Figure 21 below. Select the “Edit” button to the left of the Datasource Name that you wish to edit. Once the name change is complete, make sure to select the “Update” button to successfully update the data.

Select the “Edit” button to the left of the Datasource Name that you wish to edit. Once the name change is complete, make sure to select the “Update” button to successfully update the data.

Datasource Name	
<input type="button" value="Edit"/>	Cerner--US Legend and OTC
<input type="button" value="Edit"/>	DRPF
<input type="button" value="Edit"/>	Drugs At FDA
<input type="button" value="Update"/> <input type="button" value="Cancel"/>	
<div> <div>Name: Orange Book - approved since 1980</div> <div>Description:</div> </div> <div> <input type="button" value="Delete"/> </div>	
<input type="button" value="Edit"/>	RollNorm

Figure 21: Modify datasource names

6 Advanced Settings – Business Administrators

6.1 Manually Add Name to Database

On the Home Page, “Manually Add Name to Database” section is only available to users assigned the role of Business Administrator and is illustrated in Figure 22 below. This field allows Business Administrators to add proposed proprietary names to the POCA database which updates the datasource entitled 'Name Entered by Safety Evaluator'. Each proposed proprietary name assigned to a safety evaluator should be entered into the POCA database by a business administrator. This enables all safety evaluators to search the 'Name Entered by Safety Evaluator' datasource to find other proposed names submitted to the Agency for review which may have orthographic or phonetic similarity to the proposed name they are assigned to evaluate.

If the name is entered manually in error or spelled incorrectly, please contact business administrator to delete the incorrect entry and re-enter the correct name once the incorrect name is deleted.



Figure 22: Manually Add Name to Database

6.2 Delete Drug Name

To delete a drug name from the POCA database, click the “*Delete Drug Name*” link under *Advanced Settings* in Settings page as illustrated in Figure 23 below. The first screen in the *Delete a Record* wizard, shown below, allows you to search for a drug record in the POCA database. Enter the name of the drug you wish to delete in the text box provided and click the “Search” button. In the sample below, we searched for the name *lipitor*.

Search for the record you would like to delete using the search box below.
and then clicking the next button.

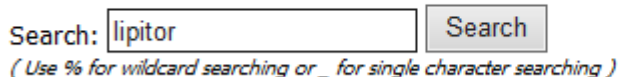


Figure 23: Delete drug name (1 of 2)

Our search returns a list of records composed of drug names and their associated data sources, as shown in the screen capture below.

Return to Settings

Search for the record you would like to delete using the search box below. Once you have found the record you are looking for, select it by clicking the circle next to the name and then clicking the next button.

Search: lipitor

(Use % for wildcard searching or _ for single character searching)

Name	Datasource
<input type="radio"/> LIPITOR	DPRF
<input type="radio"/> LIPITOR	DPRF
<input type="radio"/> LIPITOR	DPRF
<input type="radio"/> LIPITOR	DPRF
<input checked="" type="radio"/> LIPITOR	DPRF
<input type="radio"/> LIPITOR	Drugs At FDA

Figure 24: Delete a Record Screen (2 of 2)

Find the record you wish to delete and mark it for deletion by clicking the radio button to the left of the drug name. Click the “Delete” button. At the “Delete Confirmation” page, press the “Yes” button to remove the record from the POCA database or “No” button to not remove the record from the POCA database.

6.3 View SE Drug Names

To view the drugs entered by safety evaluators, click on the “View SE Drug Names” link under *Advanced Settings* in Settings page. Using the dropdown menu that appears on the screen, select the date range as illustrated in figure 25 below.

Select the Date Range you would like to view from the list below.

Show Last Month ▼

Drug Name	Date Entered	Entered By
Abasria	6/3/2013 1:30:04 PM	Walter Fava
Acticlate	6/3/2013 1:32:30 PM	Walter Fava
Aloftyn	6/3/2013 1:29:28 PM	Walter Fava
Avlina	5/31/2013 12:03:26 PM	Walter Fava
Cerinta	6/3/2013 1:31:17 PM	Walter Fava
Elifemme	6/3/2013 1:31:02 PM	Walter Fava
Hemangiol	6/3/2013 1:32:13 PM	Walter Fava
Jarbina	5/31/2013 6:59:35 AM	manizheh siahpoushan
Levemir FlexTouch	6/3/2013 2:07:37 PM	Walter Fava
Lorseva	6/3/2013 1:33:01 PM	Walter Fava
Mitigo	6/3/2013 2:06:28 PM	Walter Fava
Novolog FlexTouch	6/3/2013 2:07:16 PM	Walter Fava

Figure 25: View SE Drug Names screen

6.4 Manage Biologic suffixes data source

“Manage Biologic suffixes data source” section is only available to users assigned the role of Business Administrator. Click on the “Manage Biologic Suffixes Data Source” link under *Advanced Settings* in Settings page. It will display the page as illustrated in Figure 26 below. This page allows Business Administrators to add proposed four digit Biologic Suffixes to the POCA database which updates the datasource entitled ‘Biologic Suffixes Entered by Safety Evaluator’. This enables all users to search the ‘Biologic Suffixes Entered by Safety Evaluator’ datasource to find all stored suffixes submitted to the Agency for review which may have orthographic or phonetic similarity to the proposed names or other suffixes they are assigned to evaluate.

This page also allows Business Administrators to view the stored suffixes for specified period selected using a dropdown menu as illustrated below. By default, all suffixes that have been added during last week are displayed. The displayed suffix can be exported to a Microsoft Excel file by clicking the “Export To Excel” button.

The page also allows users to update the application number and status of the suffix as well as delete the suffix.

Add Suffix To Biologic Suffixes Data Source

Biologic Suffix:

Application Number:

Status:

☒ Under Review

☐ Approved

☐ Denied/Withdrawn

View Suffixes From Biologic Suffixes Data Source

Select the Date Range you would like to view from the list below.

Show Last Week

Total Found: 3

Biologic Suffix	Application Number	Status	Date Entered	Entered By		
SSSS	SSSS00001	Under Review	8/9/2017 4:54:39 PM	sumita biswas	Delete	Edit
BIMA	BIMAL ADDED 12	Approved	8/9/2017 4:38:01 PM	Bimal Ojha	Delete	Edit
BINA	BIMAL ADDED WW	Denied/Withdrawn	8/9/2017 4:37:50 PM	Bimal Ojha	Delete	Edit

Figure 26: Manage Biologic Suffixes Data Source Page

To add suffix to the datasource:

- Click on the “Manage Biologic Suffixes Data Source” link under the “Advanced Settings” tab.
- Put the suffix in “Biologic Suffix” text box as illustrated Figure 27.
- Put the correct “Application Number” and select the correct “Status”
- Click “Add” button
- New Suffix name will be updated to the database and it will be displayed in View section.

Add Suffix To Biologic Suffixes Data Source

Biologic Suffix:

Application Number:

Status: ☒ Under Review
☐ Approved
☐ Denied/Withdrawn

Figure 27: Adding Biologic suffix**To modify the existing suffix:**

- Select the suffix and click on the “Edit” button as illustrated in Figure 28.
- Application number will be changed to Text box and Status will be changed to radio choices. Change the application number and status of the existing suffix.
- Click on the “Update” button to save the changes. You may click on the “Cancel” button to cancel the changes.

To delete an existing suffix:

- Select the suffix.
- Click on the “Delete” button as illustrated in Figure 28.
- A pop-up will be displayed there to confirm the delete suffix .
- Click OK to confirm.
- The suffix will be deleted.

View Suffixes From Biologic Suffixes Data Source

Select the Date Range you would like to view from the list below.

Show Last Month

Total Found: 3

Biologic Suffix	Application Number	Status	Date Entered	Entered By		
SSSS	SSSS00001	Under Review	8/9/2017 4:54:39 PM	sumita biswas	Delete	Edit
BIMA	BIMAL ADDED 12	Approved	8/9/2017 4:38:01 PM	Bimal Ojha	Delete	Edit
BINA	BIMAL ADDED WW	Denied/Withdrawn	8/9/2017 4:37:50 PM	Bimal Ojha	Delete	Edit

Figure 28: Modify Biologic Suffix

7 Drug Name Searches - All Users

7.1 Search Algorithms

The POCA system has three search modules, namely *orthographic*, *phonetic*, and *text*.

The orthographic search module is implemented using an ALINE algorithm modified for orthographic purposes. The orthographic search engine does not accept wild cards, as the algorithm takes each part of a written name into account when matching against names stored in the POCA database.

The phonetic search module is implemented using an ALINE algorithm for phonetic matching. The phonetic search engine does not accept wild cards because each sound of a name is taken into account when matching against names in the POCA database. The phonetic search engine ignores the numeric and special characters in the drug name.

The combined score is calculated as the average of the orthographic and phonetic scores.

Note that both the orthographic and phonetic search engines ignore numeric and special characters included in drug names. For example, the orthographic and phonetic similarity score for 'Drug-2' and 'Drug-25' will be 100%. See Figure 26 below.

Direct Search		Direct Search	
Candidate Drug:	tylenol	Candidate Drug:	Otezla
Comparator Drug:	tylenol @\$45	Comparator Drug:	Otezla 4566
<input type="button" value="Reset"/> <input type="button" value="Submit"/>		<input type="button" value="Reset"/> <input type="button" value="Submit"/>	
Combined Score:	100	Combined Score:	100
Phonetic Score:	100	Phonetic Score:	100
Orthographic Score:	100	Orthographic Score:	100

Figure 29: search algorithm

The text search module is implemented using comparison methods for text matching built in to the Oracle 12c Database Management System. Several wildcards are available for the text search engine.

The percent sign (%) is a wildcard character that will match any sequence of consecutive characters.

For example:

Search Term: flo%in Results:

floucin, floxin

The underscore character (_) is a wildcard that will match any single character.

For example:

Search Term: flo_in

Results: floxin

Wildcard characters can be used in conjunction with each other for matching a wider variety of patterns.

For example:

Search Term: fl%x__

Results: flexin, flexon, floxin, fluanxol, flavocoxid

In the above example, both types of wild cards were used. A '%' character was used to match any sequence of characters after the 'l' character and before the 'x' character in the search term. Two underscore characters ('_') were used to match any two (2) characters at the end of a name.

7.2 Accessing the Search

The “*Drug Name Search*” section in Home page provides an easy interface to conduct searches in POCA. The Search page can also be accessed by clicking the “*Search*” link in the Navigation Bar or by clicking the “*New Search*” link in the *Options* Bar.

The “*Direct Search*” functionality is available to all users under “Direct Search” section in Home page as well as in Search page. This feature provides user the ability to do direct search between Candidate Drug and Comparator Drug. After entering those 2 drug names and pressing Submit button, the Combined, Phonetic and Orthographic score search results will be displayed for those 2 drug names.

7.3 Search View

The “*Drug Name Search*” view allows users to search the POCA drug databases for a drug name using a combination of Orthographic, Phonetic, and Text algorithms. The *Drug Name Search* is accessible directly from the Home page, or by clicking on the “Search” link in the header as shown in Figure 30 below.

By default, the orthographic and phonetic search options are preselected to run. However, you may also customize the type of search you need to run by selecting or unselecting any of the choices for Orthographic, Phonetic, or Text searches. Please note that Text searches cannot be run in combination with the two other search types, orthographic and phonetic, and must be selected by itself in order to run a text search. When performing a text search, the underscore '_' character may be used to match any single character or the percentage '%' character may be used to match any string of characters. Placing the '%' character before a letter string will identify any name ending in that exact letter string, and placing the '%' character after a letter string will identify any names beginning with that exact letter string.

Drug Name Search

* % For wildcard searching
_ For single character searching

Search Text:

Search Type: ☒ Orthographic
☒ Phonetic
☐ Text*

Datasources:






	Datasource	Date Updated	Product Count	
<input checked="" type="checkbox"/>	Drugs At FDA	06-22-2017	6,939	
<input checked="" type="checkbox"/>	RxNorm	08-08-2017	27,588	
<input checked="" type="checkbox"/>	Name Entered by Safety Evaluator	07-19-2017	75	
<input type="checkbox"/>	Biologic Suffixes Entered by Safety Evaluator	08-09-2017	3	
<input type="checkbox"/>	Cerner--US Legend and OTC	01-31-2015	10,583	
<input type="checkbox"/>	DPRF	12-12-2007	36,508	
<input type="checkbox"/>	Orange Book - approved since 1980	06-20-2017	6,628	
<input type="checkbox"/>	cber biologic	08-13-2008	350	
<input type="checkbox"/>	Jayesh 4444			

Figure 30: Drug Name Search

Drugs@FDA, RxNorm, and Name Entered by Safety Evaluator are pre-selected and by default, name searches will be run against these three datasources. Users may customize their search by unselecting or selecting any combination of datasources under the datasource column.

Once users have entered the drug name to search in the “Search” Textbox, and have selected the search type and datasources they can click on the “Submit” button or press the “Enter” key on their keyboard. If the search criteria need to be changed, users may use the “Reset” button. This feature allows users to revise their search criteria or their search name.

The search results will be calculated and filtered with the scores that are equal to and greater than the results threshold value entered by the user under the settings page in the “user’s results threshold” value. The “Search Results” page will be displayed as described in section 7 below.

7.4 Search Results

The *Search Results* page displays the results of the search based on the search criteria entered. The results will display in a table that allows users to view the names within their defined threshold for combined scores, ‘phonetic scores’, ‘orthographic scores’, and ‘all scores’, by clicking the tabs at the top of the results table labeled ‘Combined’, ‘Phonetic’, ‘Orthographic’, and ‘All’.

For example, if the phonetic and orthographic search types are specified for the search, the results will display in a table that contains tabs which will allow users to display scores

for each search type separately (‘combined’ results, ‘phonetic’ results, and ‘orthographic’ results). There is also a tab that allows user to display all three types of search results on one page. An overview of the result tabs is illustrated in Figure 28 below. It shows the *Search Results* page displaying the results of a search for *lipitor* using the orthographic and phonetic search types.

[New Search](#)

Search Results
Search Term: *lipitor*

[Export To Excel](#)

Combined **Phonetic** **Orthographic** **All**

Orthographic & Phonetic Matches greater than 50%: Results 1 - 50 of 134
70% and Higher: 3 Between 50% and 69%: 131 49% and Lower: 0

<input type="checkbox"/> Name of Concern	Match Percentage ▾	Datasource
<input type="checkbox"/> LIPITOR	100	RxNorm; Drugs At FDA
<input type="checkbox"/> Lipidro	74	RxNorm
<input type="checkbox"/> Clinitar	70	RxNorm
<input type="checkbox"/> Zador	68	RxNorm; Drugs At FDA
<input type="checkbox"/> LIPIDIL	68	Drugs At FDA
<input type="checkbox"/> Lipiodol	68	RxNorm; Drugs At FDA
<input type="checkbox"/> Lidovir	66	RxNorm
<input type="checkbox"/> Glister	66	RxNorm
<input type="checkbox"/> Flector	66	RxNorm; Drugs At FDA
<input type="checkbox"/> Lidomar	66	RxNorm
<input type="checkbox"/> Zipsor	65	RxNorm; Drugs At FDA
<input type="checkbox"/> RELISTOR	64	RxNorm; Drugs At FDA

Figure 31: Search Results Example

For searches conducted where users only select ‘Text’ as the search type, the Search Results page will display the exact text matches in a results table having only the Text tab at the top of the table.

All table columns on the *Search Results* page can be sorted by clicking on the column header.

If users would like to see additional information about any names returned by the search, click on the drug name of concern. A “Product Details” page will be displayed in new window with all product details stored in the POCA database, including the data sources, as illustrated in Figure 32 below. Please be aware that some results identified from RxNorm will not contain information in Product Details page.

Product Details for LIPITOR

Data Source	Dosage Form	Potency	Route	Active Ingredient
Drugs At FDA	TABLET; ORAL	EQ 80MG BASE/A	N/A	ATORVASTATIN CALCIUM
RxNorm	SEE ACTIVE INGREDIENT	N/AN/A	N/A	ATORVASTATIN 80 MG ORAL TABLET [LIPITOR]
Orange Book - approved since 1980	TABLET; ORAL	EQ 80MG BASE/A	N/A	ATORVASTATIN CALCIUM
Cerner--US Legend and OTC	TABLET	20MILLIGRAM(S)	ORAL	ATORVASTATIN
Drugs At FDA	TABLET; ORAL	EQ 20MG BASE/A	N/A	ATORVASTATIN CALCIUM
RxNorm	SEE ACTIVE INGREDIENT	N/AN/A	N/A	ATORVASTATIN 40 MG ORAL TABLET [LIPITOR]
Orange Book - approved since 1980	TABLET; ORAL	EQ 40MG BASE/A	N/A	ATORVASTATIN CALCIUM
Cerner--US Legend and OTC	TABLET	80MILLIGRAM(S)	ORAL	ATORVASTATIN
DPRF	TABLET	EQ 80MG BASE	ORAL	ATORVASTATIN CALCIUM
RxNorm	SEE ACTIVE INGREDIENT	N/AN/A	N/A	ATORVASTATIN 20 MG ORAL TABLET [LIPITOR]
Cerner--US Legend and OTC	TABLET	10MILLIGRAM(S)	ORAL	ATORVASTATIN
Orange Book - approved since 1980	TABLET; ORAL	EQ 20MG BASE/A	N/A	ATORVASTATIN CALCIUM
Drugs At FDA	TABLET; ORAL	EQ 40MG BASE/A	N/A	ATORVASTATIN CALCIUM
Drugs At FDA	TABLET; ORAL	EQ 10MG BASE/A	N/A	ATORVASTATIN CALCIUM
Cerner--US Legend and OTC	TABLET	40MILLIGRAM(S)	ORAL	ATORVASTATIN
RxNorm	SEE ACTIVE INGREDIENT	N/AN/A	N/A	ATORVASTATIN 10 MG ORAL TABLET [LIPITOR]
Orange Book - approved since 1980	TABLET; ORAL	EQ 10MG BASE/A	N/A	ATORVASTATIN CALCIUM

Figure 32: Product Details Page

7.5 Export To Excel

The 'Export To Excel' button displays above the search results table. Users can click on the Export to Excel button to transfer search results into an Excel Spreadsheet. This feature will export the combined scores, the phonetic scores, and the orthographic scores, as well as any product information from the product details into the Excel spreadsheet.

Also, please note that when the tab for combined search results is selected and the results are exported to Excel, the Excel spreadsheet will contain the combined, phonetic, and orthographic scores for all of the combined results as illustrated in Figure 30 below.

Otezla_CombinedSearchResults_50Percentagexls - Microsoft Excel							
Combined Search Result							
Search Term: otezla Search Date: 09/07/2016 10:14 AM							
Name of Concern	Orthographic Score	Phonetic Score	Combined Score	Data Sources	Active Ingredient	Strength	Dosage Form
Otezla	100	100	100	RxNorm; Drugs At FDA	APREMILAST	10MG 20MG 30MG	TABLET
Zotex La	85	60	72	RxNorm			
Otovel	71	67	69	RxNorm; Drugs At FDA	CIPROFLOXACIN HYDROCHLORIDE; FLUOCINOLONE ACETONIDE	EQ 0.3% BASE;0.025%	SOLUTION/DROPS
Teslac	67	70	68	RxNorm; Drugs At FDA	TESTOLACTONE	100MG/ML 250MG 50MG	INJECTABLE TABLET
Motazol	73	57	65	RxNorm	CLOTRIMAZOLE 10 MG/ML / GENTAMICIN 3 MG/ML / MOMETASONE 1 MG/ML OTIC SUSPENSION [MOTAZOL]		
Atreza	71	57	64	Name Entered by Safety Evaluator; RxNorm	ATROPINE SULFATE 0.4 MG ORAL TABLET [ATREZA]		
Teflaro	69	52	60	RxNorm; Drugs At FDA	CEFTAROLINE FOSAMIL	400MG/VIAL 600MG/VIAL	POWDER
Telazol	81	40	60	RxNorm	TILETAMINE 50 MG/ML / ZOLAZEPAM 50 MG/ML INJECTABLE SOLUTION [TELAZOL]		
Entex La	65	55	60	RxNorm			
Savella	54	64	59	Name Entered by Safety Evaluator; RxNorm; Drugs At FDA	MILNACIPRAN HYDROCHLORIDE	100MG 12.5MG 25MG 50MG	TABLET

Orthographic Search Result						
Search Term: otezla			Search Date: 09/07/2016 10:13 AM			
Name of Concern	Orthographic Score	Data Sources	Active Ingredient	Strength	Dosage Form	Route
Otezla	100	RxNorm; Drugs At FDA	APREMILAST	10MG 20MG 30MG	TABLET	ORAL
Zotex La	85	RxNorm				
Telazol	81	RxNorm	TILETAMINE 50 MG/ML / ZOLAZEPAM 50 MG/ML INJECTABLE SOLUTION [TELAZOL]			
Terazol 3	77	RxNorm; Drugs At FDA	TERCONAZOLE	0.80% 80MG	CREAM SUPPOSITORY	VAGINAL
Terazol 7	77	RxNorm; Drugs At FDA	TERCONAZOLE		0.40% CREAM	VAGINAL
Oxtellar	75	RxNorm	24 HR OXCARBAZEPINE 150 MG EXTENDED RELEASE ORAL TABLET [OXTELLAR] 24 HR OXCARBAZEPINE 300 MG EXTENDED RELEASE ORAL TABLET [OXTELLAR] 24 HR OXCARBAZEPINE 600 MG EXTENDED RELEASE ORAL TABLET [OXTELLAR]			

Figure 33: Export to Excel examples

When users click on the ‘Export to Excel’ button, a pop up window appears at the bottom of the screen asking if you want to open or save your search results as illustrated in Figure 31 below. If users click on the dropdown arrow next to the ‘Save’ tab, a menu appears for users to select from either ‘Save’, ‘Save as’, or ‘Save and Open’. Select ‘Save as’ and the data will be saved in a

Search Results
Search Term: zonalon

Export To Excel

Combined **Phonetic** **Orthographic** **All**

Phonetic Matches greater than 50%: Results 1 - 99 of 438
70% and Higher: 22 Between 50% and 69%: 416 49% and Lower: 0

Name of Concern	Match Percentage	Datasource
ZONALON	100	RxNorm; Drugs At FDA
VANILLIN	82	RxNorm
CINALOG	77	RxNorm
ZEVALIN	75	Drugs At FDA
BUTALAN	74	Drugs At FDA
DEMULEN	74	RxNorm
DEMULEN 1/35	74	RxNorm
DEMULEN 1/35-21	74	Drugs At FDA
DEMULEN 1/35-28	74	Drugs At FDA
DEMULEN 1/50	74	RxNorm
DEMULEN 1/50-21	74	Drugs At FDA
DEMULEN 1/50-28	74	Drugs At FDA

Do you want to open or save zonalon_PhoneticSearchResults.xls (200 KB) from poca.dev.fda.gov?

Open Save Save as Save and open

Figure 34: Excel file 'Save as' in the local drive

file with a ‘.xls’ extension appearing after the file name. This format will allow users to easily edit the information in the spreadsheet. If users choose only to open the spreadsheet, but later decide to save it, they will need to click on the ‘File’ tab in the upper left hand corner of toolbar, select ‘Save as’, and from the dropdown menu, choose the version of Excel with the file extension, ‘.xls’ or the file extension compatible with the most current version of Excel in their computer.